DEC 22 2000

510(k) SAFETY AND EFFECTIVENESS SUMMARY

K001955

Trade Name:	Aaron A1250-A, A1250-A/240, A1250-B, A1250-B/240, A1250-C, A1250-C/240, and A1250-D, A1250-D/240 High Frequency Electrosurgical Generator
Common Name:	Electrosurgical Generator
Classification Name:	Electrosurgical Cutting and Coagulation Devices and Accessories (per 21CFR 878.4400)

The **Aaron 1250 High Frequency Electrosurgical Generator** is a non-sterile, reusable electrosurgical generator, which is designed to generate high frequencies (RF) of high voltage and low amperage current.

The **Aaron 1250 High Frequency Electrosurgical Generator** is intended to be used for all electrosurgical cut, blend, coagulation, fulguration, and bipolar procedures.

The **Aaron 1250 High Frequency Electrosurgical Generator** is substantially equivalent to the Aaron Medical **Aaron 1200 High Frequency Electrosurgical Generator (K980366)** in operation, intended use, materials, energy source, output, components, method of preparation, and performance claims. The **Aaron 1250 High Frequency Electrosurgical Generator** incorporates duel rotary dial-selected or duel up-down push button-selected energy output, allowing independent setting of cut and coagulation mode energy (the Aaron 1200 has a single rotary dial and a single LED window). The **Aaron 1250** is available with or without patient split pad sensing capability.

Testing performed on the **Aaron 1250** indicates that the device is substantially equivalent in its performance and method of operation.

Hazard analysis evaluations are performed on the **Aaron 1250**. There are no new hazards presented with the use of the **Aaron 1250** as compared with the predicate devices.

In conclusion, the **Aaron 1250** High Frequency Electrosurgical Generator is substantially equivalent to the predicate device (Aaron 1200) in methods of operation, intended use, and results derived from operation.

Submitted By: Richard Kozloff
Vice-President ; Quality Assurance
Aaron Medical Industries
7100 30th Avenue North
St. Petersburg, FL 33710

Contact Person: Richard Kozloff
Date: June 23, 2000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 2000

Mr. Richard Kozloff
Vice President, Quality Assurance
and Regulatory Affairs
Aaron Medical Industries
7100 30th Avenue, North
St. Petersburg, Florida 33710

Re: K001955
Trade Name: Aaron A1250-A, A1250-A/240, A1250-B, A1250-B/240, A1250-C, A1250-C/240, and A1250-D, A1250-D/240 High Frequency Electrosurgical Generator
Regulatory Class: II
Product Code: GEI
Dated: November 29, 2000
Received: November 30, 2000

Dear Mr. Kozloff:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

AARON MEDICAL INDUSTRIES **510 (K) NOTIFICATION**
AARON 1250 HIGH FREQUENCY GENERATOR

INDICATIONS FOR USE

510(k) Number (if known): K001955

Device Name: Aaron A1250-A, A1250-A/240, A1250-B, A1250-B/240, A1250-C, A1250-C/240, and A1250-D, A1250-D/240 High Frequency Electrosurgical Generator

Indications for Use:

The Aaron 1250 High Frequency Electrosurgical Generator models are intended to be used for all electrosurgical cut, blend, coagulation, fulguration, and bipolar procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(K) Number 001955

(Optional Format 3-10-98)